UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: October 6, 2011

SUBJECT: Secondary Review of Contractor's (DynCorp Systems & Solutions LLC) Efficacy Review for CaviWipes 1;
EPA File Symbol 46781-RG;
DP Barcode: D392313

FROM: Lorilyn M. Montford LM 10/6/11
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THRU: Dr. Tajah Blackburn, Team Leader
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Lorilyn Montford for Tajah Blackburn 10/6/11

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APPLICANT: Metrex Research
28210 Wick Road
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FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Didecyldimethylammonium chloride	0.76%
Ethanol	7.5%
Isopropanol	15.0%
Inert Ingredients	76.74%
Total	100.00%

I BACKGROUND

The product, CaviWipes 1 (EPA File Symbol 46781-RG), is a new product. The applicant requested to register the towelette product for use as a disinfectant (bactericide, fungicide, tuberculocide, virucide) and deodorizer on hard, non-porous surfaces in household, institutional, commercial, food preparation, animal care, and hospital or medical environments. The label states that the product is a "one-step" disinfectant. Studies were conducted at MICROBIOTEST, located at 105 Carpenter Drive in Sterling, VA 20164. This data package contained nine studies (MRID 485285-01 through 485285-09), Statements of No Data Confidentiality Claims for all nine studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: ambulance equipment, appliance exteriors, barber and salon instruments, basins, bassinets, bathroom fixtures, bathtubs, bed railings, cabinets, cages, carts, chairs, computer keyboards, computers, countertops, cribs, diaper changing stations, diaper pails, diagnostic equipment, doorknobs, faucets, filing cabinets, floors, garbage cans, grocery carts, gurneys, hampers, hand rails, handles, headsets, health club equipment, high chairs, infant incubators, infant warmers, kennels, laboratory equipment and surfaces, lamps, light switches, lights, nail care implements, oxygen hoods, patient monitoring equipment, physical therapy equipment, shower stalls, showers, sinks, spine backboards, stethoscopes, stretchers, tables, tanning beds, telephones, toilets, toys, trash cans, trays, ultrasound transducers, urinals, vanity tops, walls, walkers, wheelchairs, whirlpools, and work stations. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: Formica, glass, glazed tile, painted surfaces, plastic (e.g., polycarbonate, polypropylene, polyvinylchloride, polystyrene, vinyl), Plexiglas, and stainless steel. Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Use one towelette to completely pre-clean surface of all gross debris. Use a second towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 1 minute.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 485285-01 "Initial Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – June 17, 2011. Laboratory Project Identification Number 198-628.

This study, under the direction of Study Director S. Steve Zhou, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (ducklings obtained from Metzer Farms) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Initial Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Two replicates were tested for each product lot. Each carrier was divided into three sections for

treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 21°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 1% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using L-15 Complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO_2 for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for an additional 9-13 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

2. MRID 485285-02 "Confirmatory Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)" for CaviWipes 1, by Helen Christina. Study conducted at MICROBIOTEST. Study completion date – June 17, 2011. Laboratory Project Identification Number 198-629.

This confirmatory study, under the direction of Study Director Helen Christina, was conducted against Duck hepatitis B virus (Strain LeGarth; obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes (ducklings obtained from Metzer Farms) as the host system. One lot (Lot No. 11-1125) of the product, CaviWipes 1, was tested according to a MICROBIOTEST protocol titled "Confirmatory Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Two replicates of the single product lot were tested. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 21°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 1% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using L-15 Complete. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO_2 for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for an additional 9-13 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the infectious virus was assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (the single product lot). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

3. MRID 485285-03 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Human Immunodeficiency Virus Type 1" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – May 31, 2011. Laboratory Project Identification Number 198-630.

This study was conducted against Human immunodeficiency virus type 1 (strain not specified; obtained from ZeptoMetrix Corporation), using C8166 cells (obtained from the University of Pennsylvania) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Human Immunodeficiency Virus Type 1," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using RPMI 1640 with 5% fetal bovine serum. C8166 cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 9-12 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

4. MRID 485285-04 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Herpes Simplex Virus Type 1" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – May 31, 2011. Laboratory Project Identification Number 198-631.

This study was conducted against Herpes simplex virus type 1 (ATCC VR-260), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Herpes Simplex Virus Type 1," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 52 minutes at room temperature. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of newborn calf serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were

prepared, using RPMI 1640 with 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 5-8 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

5. MRID 485285-05 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Herpes Simplex Virus Type 2" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – May 31, 2011. Laboratory Project Identification Number 198-632.

This study was conducted against Herpes simplex virus type 2 (ATCC VR-734), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Herpes Simplex Virus Type 2," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of newborn calf serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.1N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using RPMI 1640 with 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 5-8 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

6. MRID 485285-06 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Human Influenza A Virus" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – May 31, 2011. Laboratory Project Identification Number 198-633.

This study was conducted against Human influenza A virus (Strain A/PR/8/34 (H1N1); obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Human Influenza A Virus," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum

over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 45 minutes at room temperature. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of Minimum Essential Medium with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 1.0 µg/mL Trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were washed with phosphate buffered saline prior to inoculation, as necessary. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

7. MRID 485285-07 "Initial Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C virus)" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – May 31, 2011. Laboratory Project Identification Number 198-635.

This study, under the direction of Study Director S. Steve Zhou, was conducted against Bovine viral diarrhea virus (strain not specified; obtained from American BioResearch Laboratories), using MDBK cells (ATCC CCL-22) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Initial Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Two replicates were tested per product lot. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of horse serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCL. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 5% horse serum. MDBK cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 5-7 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

8. MRID 485285-08 "Confirmatory Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C virus)" for CaviWipes 1, by David Kang. Study conducted at MICROBIOTEST. Study completion date – May 31, 2011. Laboratory Project Identification Number 198-636.

This confirmatory study, under the direction of Study Director David Kang, was conducted against Bovine viral diarrhea virus (strain not specified; obtained from American BioResearch Laboratories), using MDBK cells (ATCC CCL-22) as the host system. One lot (Lot No. 11-1126) of the product, CaviWipes 1, was tested according to a MICROBIOTEST protocol titled "Confirmatory Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Two replicates of the single product lot were tested. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of horse serum with 1% Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 5% horse serum. MDBK cells in multi-well culture dishes were inoculated eight-fold with the dilutions. The cultures were incubated for 5-7 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (the single product lot). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

9. MRID 485285-09 "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test, Human Coronavirus" for CaviWipes 1, by S. Steve Zhou. Study conducted at MICROBIOTEST. Study completion date – June 6, 2011. Laboratory Project Identification Number 198-637.

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using MRC-5 cells (ATCC CCL-171) as the host system. Two lots (Lot Nos. 11-1125 and 11-1126) of the product, CaviWipes 1, were tested according to a MICROBIOTEST protocol titled "Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test - Human Coronavirus," dated May 16, 2011 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The viral stock contained at least a 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes (10 square inches). The virus films were dried for 50 minutes at room temperature. Each carrier was divided into three sections for treatment: top, middle, and bottom. Each section was wiped left to right and back again to the left. A different area of each towelette was used for each section. The carrier was rotated 90 degrees and the wiping process was repeated. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 1 minute at 20°C. Following exposure, each plate was neutralized with 1.0 mL of fetal bovine serum with 1%

Polysorbate 80, 0.5% Lecithin, 10% HEPES, and 0.01N HCl. Each plate was scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 5% fetal bovine serum. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 5-7 days at 33±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

V RESULTS

MRID Number	Organism	Results			Plate Recovery Control (average load per carrier)
			Lot No. 11-1125	Lot No. 11-1126	
1-Minute Exposure Time					
485285-01	Duck hepatitis B virus	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{5.80}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/ carrier	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		Log reduction	≥ 3.30 $\log_{10}$	≥ 3.30 $\log_{10}$	
485285-02	Duck hepatitis B virus	10^{-1} to 10^{-2} dilutions	Cytotoxicity	---	$10^{5.94}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-6} dilutions	Complete inactivation	---	
		$TCID_{50}$/ carrier	$\leq 10^{2.50}$	---	
		Log reduction	≥ 3.44 $\log_{10}$	---	
485285-03	Human immunodeficiency virus type 1	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{7.85}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/ carrier	$\leq 10^{3.80}$	$\leq 10^{3.80}$	
		Log reduction	≥ 4.05 $\log_{10}$	≥ 4.05 $\log_{10}$	
485285-04	Herpes simplex virus type 1	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{7.35}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	

MRID Number	Organism	Results			Plate Recovery Control (average load per carrier)
			Lot No. 11-1125	Lot No. 11-1126	
		$TCID_{50}$/ carrier	$\leq 10^{3.80}$	$\leq 10^{3.80}$	
		Log reduction	≥ 3.55 $\log_{10}$	≥ 3.55 $\log_{10}$	
485285-05	Herpes simplex virus type 2	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{7.35}$ $TCID_{50}$/ carrier
		10^{-2} dilution	Slight cytotoxicity observed w/viral CPE	Cytotoxicity	
		10^{-3} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/ carrier	$\leq 10^{2.80}$	$\leq 10^{3.80}$	
		Log reduction	≥ 4.55 $\log_{10}$	≥ 3.55 $\log_{10}$	
485285-06	Human influenza A virus	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{6.80}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/ carrier	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		Log reduction	≥ 4.30 $\log_{10}$	≥ 4.30 $\log_{10}$	
485285-07	Bovine viral diarrhea virus	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{7.54}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/ carrier	$\leq 10^{3.80}$	$\leq 10^{3.80}$	
		Log reduction	≥ 3.74 $\log_{10}$	≥ 3.74 $\log_{10}$	
485285-08	Bovine viral diarrhea virus	10^{-1} to 10^{-2} dilutions	---	Cytotoxicity	$10^{7.24}$ $TCID_{50}$/ carrier
		10^{-3} to 10^{-6} dilutions	---	Complete inactivation	
		$TCID_{50}$/ carrier	---	$\leq 10^{3.80}$	
		Log reduction	---	≥ 3.44 $\log_{10}$	
485285-09	Human coronavirus	10^{-1} to 10^{-2} dilutions	Cytotoxicity	Cytotoxicity	$10^{6.80}$ $TCID_{50}$/

MRID Number	Organism	Results			Plate Recovery Control (average load per carrier)
			Lot No. 11-1125	Lot No. 11-1126	
		10^{-3} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	carrier
		$TCID_{50}$/ carrier	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		Log reduction	≥ 4.30 $\log_{10}$	≥ 4.30 $\log_{10}$	

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, CaviWipes 1, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of at least a 5% organic soil load (a 100% organic soil load for Duck hepatitis B virus) for a 1-minute contact time:

Duck hepatitis B virus	MRID 485285-01 and -02
Human immunodeficiency virus type 1	MRID 485285-03
Herpes simplex virus type 1	MRID 485285-04
Herpes simplex virus type 2	MRID 485285-05
Human influenza A virus	MRID 485285-06
Bovine viral diarrhea virus	MRID 485285-07 and -08
Human coronavirus	MRID 485285-09

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was observed in the 10^{-1} and 10^{-2} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. In studies against Duck hepatitis B virus and Bovine viral diarrhea virus, the initial and confirmatory studies were performed at the same laboratory but under the direction of different study directors. The confirmatory studies tested one product lot, not the standard two product lots.

VII RECOMMENDATIONS

1. The proposed label claims that the towelette product, CaviWipes 1, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of light to moderate soil loads for a 1-minute contact time:

Hepatitis B virus
Hepatitis C virus
Human immunodeficiency virus type 1
Herpes simplex virus type 1
Herpes simplex virus type 2
Human coronavirus

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the towelette product, CaviWipes 1, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of light to moderate soil loads for a 1-minute contact time (for a 3-minute contact time against Adenovirus II):

Staphylococcus aureus
Pseudomonas aeruginosa
Salmonella enterica
Acinetobacter baumannii
Klebsiella pneumoniae
Bordetella pertussis
Methicillin Resistant *Staphylococcus aureus*
Methicillin Resistant *Staphylococcus epidermidis*
Vancomycin Resistant *Enterococcus faecalis*
Vancomycin Intermediate *Staphylococcus aureus*
ESBL *Escherichia coli*
Trichophyton mentagrophytes
Candida albicans
Mycobacterium tuberculosis var: bovis
Adenovirus II (3 minute contact time)

These claims are acceptable as data was provided in a previous submission to support these claims.